neoteryx®
by TRAJAN

Mitra® 96-Autorack™ (RUO)

TRAJAN Trajan Scientific and Medical

www.neoteryx.com

EN **Instructions for Use**

Mitra® 96-Autorack™ (RUO)

IMPORTANT – Read the entire instructions before use!

These instructions apply to the following Mitra® Device configurations:
- Mitra 96-Autorack

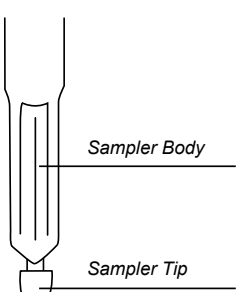
Intended Use:

A single-use, non-sterile device used as a specimen collector, and for the storage and transport of blood and other biological fluids for analytical and diagnostic analyses for Research Use Only (RUO).

Device Description:

The Mitra 96-Autorack Device is designed to be used by laboratory professionals or healthcare professionals.

The blood sample is typically taken from a container (e.g. tube). The sampler tip (contained within the Mitra Device) is gently applied to the surface of the blood until the entire sampler tip turns red indicating a volumetric sample (10, 20, or 30 µL depending on the device being used) has been collected. This process is repeated for each sampler tip in the device.



Materials Provided:

- Mitra 96-Autorack
- Collection plate
- Sample ID Barcode (if requested)

Product Specifications:

- Sample Type: Dried Whole Blood and other biological fluids
- Sample Volume: 10, 20, or 30 µL
- Substrate: Hydrophilic porous polymer
- Volumetric Precision (%RSD): ≤ 5%
- Typical sampling event (per sampling tip size): 8 sec (10, 20 µL) – 12 sec (30 µL)
- Number of Samples Collected: Up to 96
- Shelf Life: Refer to expiry date on product label
- Device Storage: Up to 30°C
- Sample Storage: The guidelines for sample storage are analyte dependent and will need to be determined by device end-user

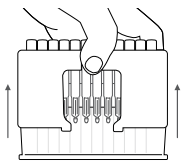
Warnings and Precautions:

- Single use only for a single individual.
- Do not use after expiration date.
- For external use only.
- Devices should be transported/mailed to the analytical laboratory, and appropriate documentation maintained according to local regulations and the analytical laboratory procedures and policies.
- Do not use if device packaging has been opened or damaged.
- Laboratories must validate use of product for their specific assay.
- Observe universal biological risk precautions.
- All used materials with blood residues must be handled and disposed of safely in accordance with local regulations.
- Please reach out to neo.support@trajanscimed.com for alternative instructions of the collection of other biological fluid. Dried biological fluids can be dried and safely transported as per instructions contained in this IFU.
- Any serious incident in relationship with the Mitra device should be reported as soon as possible to Trajan Scientific and Medical (neo.support@trajanscimed.com) and the competent authority of the Member State in which the user and/or patient is established.
- Please reach out to neo.support@trajanscimed.com in case of multiple under-sampling events.

WATCH –
Instructional videos at www.neoteryx.com/collect or scan the QR code to access.

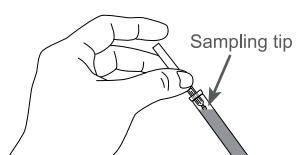
Instructions for Blood Sampling:

1. Remove 96-Autorack from the collection plate it is resting in by lifting the 96-Autorack up. Set the 96-Autorack down next to the collection plate.



2. Remove a sampler from the 96-Autorack and touch sampling tip to surface of blood sample.

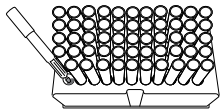
   Watch sampling tip go FULLY red and then count 2 seconds. SLOWLY and SMOOTHLY remove sampling tip from blood.



IMPORTANT!

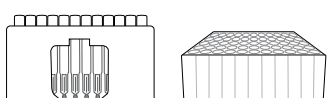
- **Do NOT fully submerge the sampler tip in blood.**
- **Sampler tip should always point downward towards floor as illustrated.**
- **Do NOT drip blood onto the sampler tip.**
- **Ensure sampler tips are filled correctly (Figure 1).**

3. Return sampler to 96-Autorack. Repeat step 2 for remaining samplers. Do not touch side walls of 96-Autorack with sampling tip upon entry.

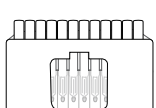


4. Dry sampling tips in 96-Autorack under ambient conditions (~ 3 hours).

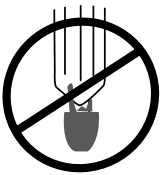
   Note: The collection plate should ALWAYS be removed from the 96-Autorack during the drying process to allow air to freely circulate around microsamplers. Wait a minimum of 3 hours to ship to ensure dryness of sampling tips.



5. Dried samplers can be returned to the collection plate.

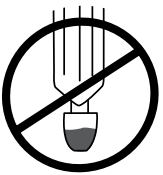


Ensure sampler tips are filled correctly.



Over-sampling occurs when:

1. Blood is dripped onto the sampler tip from above.
2. The entire sampler tip is submerged into the blood specimen.



Under-sampling occurs when:

1. The sampler tip is removed from the blood too soon. Touch tip to blood until no white remains.
2. Refer to Warnings and Precautions section in case of multiple under-sampling events.

Correctly sampled

Figure 1

For further assistance, please do not hesitate to contact us: neo.support@trajanscimed.com

Specifications are subject to change.

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RUO

30°C